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PATENT
Customer No. 22,852
Attorney Docket No: 03495.0008-08

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| In re application of | ) | |
| | ) | |
| Marc ALIZON et al. | ) | Group Art Unit: 1648 |
| | ) | |
| Serial No.: 08/384,248 | ) | Examiner: J. PARKIN |
| | ) | |
| Filed: February 6, 1995 | ) | |
| | ) | |
| For: METHOD OF PRODUCING ANTIBODIES TO ANTIGENS OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV 1) | ) | Confirmation No.: 9162 |

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**SUPPLEMENTAL REPLY BRIEF**

In response to the Supplemental Examiner's Answer dated March 12, 2004, appellants submit the following remarks.

## REMARKS

In an Order dated December 17, 2001, the Board remanded the application to the Examiner "to review all arguments presented in the Appeal Brief and Reply Brief and prepare an appropriate communication setting forth the examiner's reasoned response to appellant's position on appeal." (Paper No. 46 at 2.) The Board authorized a supplemental examiner's answer. (*Id.* at 3.) This Supplemental Reply Brief responds to the Examiner's position as clarified in the Supplemental Examiner's Answer dated March 12, 2004.

## I. Issues Resolved By Supplemental Examiner's Answer

In the Supplemental Examiner's Answer, the Examiner stated that "[t]he summary of invention contained in the brief is correct" and "[t]he appellants' statement of the issues in the brief is correct." (Supplemental Examiner's Answer at 2.) Accordingly, the Examiner does not dispute the accuracy of these sections of the Brief, or the statements contained therein. Thus, appellants' request that the Board adopt the statements in each of these sections.

## II. The Examiner's Position Is Based On Legally Flawed Premises

In the Supplemental Examiner's Answer, the Examiner clarified his position on the rejection of claims 34-36 under 35 U.S.C. § 112, first paragraph. It is now apparent that the Examiner dismissed appellants' arguments based on two premises.

Both of these premises are legally incorrect. Without these premises, the Examiner's position collapses, resulting in the inescapable conclusion that appellants have fulfilled the requirements of 35 U.S.C. § 112, first paragraph, for claims 34-36. The rejection of claims 34-36 should be reversed.

### A. The Examiner's Premise That Appellants Do Not Fulfill The Requirements Of 35 U.S.C. § 112, First Paragraph, Because Of A Lack Of Nucleotide Sequence Information Is In Error

The first premise relied on by the Examiner in dismissing appellants' arguments is that appellants did not know for sure that the claimed fragments weren't defective in some way since appellants did not include the nucleotide sequence of the claimed fragments in the application. (Supplemental Examiner's Answer at 6.) This premise is used by the Examiner to dismiss appellants' arguments in sections A and B of the Brief. (*Id.* at 6-7.) This premise is legally defective.

#### 1. The Examiner's Attempt To Transfer The Office's Burden To Appellants Is Improper

The Examiner has attempted to transfer the Office's burden to appellants. Appellants' specification indicates that the claimed fragments encode antigens. (Specification at 4, line 27, through 5, line 36.) The Examiner has no reason to doubt the truth and accuracy of appellants' disclosure. Moreover, the Examiner has not provided any evidence to support his allegations, but has simply relied on unsupported conjecture

that there might have been some unidentified defect in appellants' claimed fragments. This is legally insufficient. *See In re Wertheim*, 541 F.2d at 265, 191 U.S.P.Q. at 98; *see also In re Marzocchi*, 439 F.2d at 223, 169 U.S.P.Q. at 370. The Office has not met its burden because the Office has relied on unsupported speculation, which runs contrary to appellants' specification and the evidence of record.

**2. The Examiner's Allegation That Appellants' Fragments Might Be Defective Is Refuted By The Evidence Of Record**

While the Examiner's premise rests on his allegation that there might have been some unidentified defect in appellants' claimed fragments, the evidence of record refutes the Examiner's position. For example, Wain-Hobson et al., submitted as Exhibit 2 with appellants' March 21, 1997, Amendment, demonstrates that appellants' claimed fragments do, in fact, encode HIV-1 antigens. The Examiner has never addressed this fact. In view of this uncontroverted evidence, the Examiner's unsupported position is untenable.

**3. Nucleotide Sequence Information Is Not Required For Appellants To Fulfill The Written Description Requirement**

The Court of Appeals for the Federal Circuit has recently held that inclusion of a nucleotide sequence in a patent application is not required to fulfill the written description requirement of 35 U.S.C. § 112, first paragraph, if a biological

deposit of the nucleic acid material has been made. *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1326, 63 U.S.P.Q.2d 1609, 1614 (Fed. Cir. 2002)("reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement.").

Appellants' specification describes a full-length clone of HIV-1, termed "λ-J19." (Specification at Fig. 2.) Appellants' specification describes that λ-J19 was deposited at the Collection Nationale des Cultures de Micro-organismes. (*Id.* at 14, lines 23-27.) As in *Enzo*, appellants' reference in the specification to the deposit of λ-J19 describes the sequence of this HIV-1 clone sufficiently to the public for purposes of meeting the written description requirement. *See Enzo*, 296 F.3d at 1326, 63 U.S.P.Q.2d at 1614. In *Enzo*, the court stated:

> A person of skill in the art, reading the accession numbers in the patent specification, can obtain the claimed sequences from the ATCC depository by following the appropriate techniques to excise the nucleotide sequences from the deposited organisms containing those sequences.

*Id.* The same is true in the present case. Appellants' claimed fragments can be excised from the deposited plasmid by following the techniques described in appellants' specification. Consequently, the Examiner's reliance on the lack of nucleotide sequence information in the specification to support the rejection is in error.

In view of the above errors in the premise used by the Examiner in dismissing appellants' arguments in sections A and B of the Brief, the Examiner's position that appellants did not describe proteins and polypeptides encoded by the restriction fragments recited in claims 34-36 collapses. The Examiner's position is unsupported.

**B. The Examiner's Premise That Appellants Do Not Fulfill The Requirements Of 35 U.S.C. § 112, First Paragraph, Because Of A Lack Of A Working Example Is In Error**

The second premise relied on by the Examiner in dismissing appellants' arguments is that appellants' description in the specification is inadequate because the specification does not indicate that appellants actually generated the claimed antigens and antibodies. (Supplemental Examiner's Answer at 4, last ¶, and at 7-8.) In other words, the Examiner has dismissed the passages cited by appellants as supporting the claimed invention because they do not contain a working example. In effect, the Examiner indicated that nothing short of a working example is satisfactory to fulfill the written description requirement of 35 U.S.C. § 112 for claims 34-36. The Examiner's position contravenes current legal precedent.

### 1. A Working Example Is Not Required For Appellants To Fulfill The Written Description Requirement

As detailed below, cases decided by the Court of Appeals for the Federal Circuit and by the Supreme Court make clear that appellants need not provide a working example to fulfill the written description requirement.

#### a. *Gould v. Quigg* Precludes The Examiner's Requirement For A Working Example

The Court of Appeals for the Federal Circuit has held that the mere fact that something has not previously been done is not a sufficient basis for rejecting all applications purporting to disclose how to do it. *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 U.S.P.Q.2d 1302, 1304 (1987). If a working example is required to fulfill 35 U.S.C. § 112, first paragraph, the holding in *Gould* would be moot. Accordingly, the Office's basis for this rejection is in error.

#### b. The Examiner's Requirement For A Working Example Of An Antibody Cannot Stand In View Of *Noelle v. Lederman*

In *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 U.S.P.Q.2d 1508, 1514 (2004), the Federal Circuit found that an applicant can claim an antibody by its binding affinity to an antigen if the applicant has disclosed a "*fully characterized* antigen." A "*fully characterized* antigen" is disclosed "either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository." *Id.* Appellants

have disclosed a "*fully characterized* antigen" by depositing the DNA encoding the claimed antigens.

In *Noelle*, it was not necessary for the applicant to have "actually prepared" the antibody to claim it. It was sufficient to have fully described the antigen, and such a description could be accomplished through a deposit of the antigen.

According to *Noelle*, appellants do not need to have a working example of making antibodies against the claimed antigens to meet the written description requirement. Rather, they can meet the requirements of 35 U.S.C. § 112, first paragraph, by having an adequate deposit. In the present case, appellants deposited a full-length clone of HIV-1, termed "λ-J19," at the Collection Nationale des Cultures de Micro-organismes. Appellants also provided a restriction map of this clone showing the location of the claimed fragments. (Specification at Fig. 2.) Reference in the specification to the deposit of λ-J19, and how to excise the nucleotide sequence from the deposit, describes the sequence of this HIV-1 clone sufficiently to the public for purposes of meeting the written description requirement. *See Enzo*, 296 F.3d at 1326, 63 U.S.P.Q.2d at 1614. Appellants' specification fulfills the requirements of 35 U.S.C. § 112, first paragraph, for claims 34-36.

### c. *Pfaff v. Wells Electronics, Inc.* Leaves No Doubt That Appellants Can Fulfill The Written Description Requirement Without A Working Example

The Supreme Court has explicitly stated that "it is well settled that an invention may be patented before it is reduced to practice." *Pfaff v. Wells Electronics Inc.*, 48 U.S.P.Q.2d 1641, 1644 (1998). Thus, a working example (*i.e.*, reduction to practice) cannot be required to fulfill 35 U.S.C. § 112, first paragraph.

Moreover, in *Pfaff*, the Court indicated that an invention was ready for patenting when the inventor prepared a description of the invention that was sufficiently specific to enable a person skilled in the art to practice the invention. *Id.* at 1647. The Court found that Pfaff's invention was ready for patenting when Pfaff made drawings that fully disclosed the invention, not when a working example was made. *Id.* The Court's reasoning in *Pfaff* is directly applicable to appellants' invention.

Pfaff's invention was "ready for patenting" without a working example. *Id.* at 1647. Consequently, Pfaff must have had a description of the invention that fulfilled 35 U.S.C. § 112, first paragraph, without a working example. Likewise, appellants can fulfill 35 U.S.C. § 112, first paragraph, without a working example.

### C. The Rejection Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

In view of the above errors in the premises used by the Examiner in dismissing appellants' arguments in the Brief, the Examiner's position that appellants did not describe the invention of claims 34-36 collapses. The Examiner's position is unsupported. Reversal of the rejection is respectfully requested.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: _____

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